



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Nyle ELLIOTT et al.

Group Art Unit: **3763**

Serial No: **10/720,213**

Examiner: **Manuel A. Mendez**

Filed : **November 25, 2003**

For : **SINGLE USE CATHETER**

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In the Office Action of April 6, 2006, the Examiner rejected claims 1-4 and 7-8 over the combination of Kelly in view of Thornton, Meythaler et al., Stone, and Binard et al. The Examiner stated that Kelly disclosed all the elements of the claim, except for the filters. The Examiner relied upon Thornton, Meythaler and Stone for the use of various filters. Also, the Examiner stated that Binard et al. demonstrates that it is conventional to sever the proximal section of a catheter shaft when the inflation lumen becomes obstructed. This rejection is respectfully traversed.

The specification discloses a catheter having a balloon that is inflated through a lumen. A one-way valve in the inflation lumen allows inflation of the balloon, but prevents deflation. In order to deflate the balloon, the lumen must be cut. This insures that the catheter may only be used once. Claims 1 and 7 recite a one-way port allowing inflation of the cuff but not allowing deflation, whereby the first conduit *must* be cut to deflate said cuff.

Kelly discloses a catheter having a balloon 30 which is inflated through a port having a valve 20 best seen in Figures 6 and 7. This valve is not a one-way valve as it allows inflation and deflation of the balloon as explicitly stated in column 4, lines 37-38, which states "The valve 20 can be inflated and deflated directly with a hypodermic syringe 40" The patent also discloses a valve 52 which operates in the same manner, but uses a standard Luer tip syringe without a needle. As stated in column 5, lines 43-45, when discussing valve 52, "When the balloon is to be deflated, the tip is again inserted until it opens the slit whereupon the air is released into the syringe."

While Kelly does not disclose the one-way port disclosed and claimed in the application and Binard does not cure this deficiency. Binard discloses a catheter with a safety deflation means where the balloon *may* be deflated through the deflation movement by severing the catheter shaft adjacent its proximal end when the inflation movement is obstructed. But Binard et al. does not disclose a one-way port allowing inflation but preventing deflation through the port. Column 2, lines 39-42 discloses "... an inflation lumen extending between the inside of the balloon and adjacent the proximal end of the shaft, and valve means for controlling inflation and deflation of the balloon." Both Kelly and Binard et al. disclose two-way valves, allowing both inflation and deflation of the balloon and therefore no prior art, taken alone or in combination, discloses or suggests the limitations in claims 1 and 7 regarding a one-way port preventing deflation of the balloon and necessitating cutting of the catheter for removal and insuring its single use.

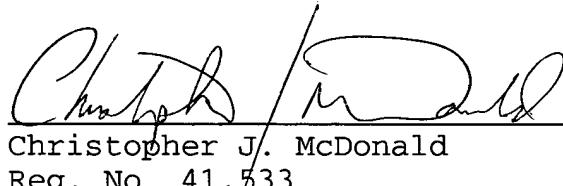
The distinction between a catheter with a two way valve, such as Kelly and Binard et al., and a one way valve, as the invention, is a direct result of their respective functions. The catheters disclosed by both Kelly, a cholangiography inserted in a

bile duct, and Binard, urinary drainage catheter, are designed to be reused. The catheter of the invention, a rectal catheter, may only be used once. The one way valve requires the catheter be cut for removal and not reused.

It is respectfully requested that the rejection be withdrawn and the application be allowed to issue. If any issues remain, and the Examiner believes a telephone conversation would resolve such issues, the Examiner is urged to contact the undersigned attorney.

If any fees are due and owing, the Commissioner is authorized to charge Deposit Account No. 08-2455.

Respectfully submitted,



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April 25, 2006

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